Amendment

In the Claims

1. (Currently amended) A method for making ~~dry,~~ micronized particles of an agent, comprising:

(a) dissolving a macromolecular material in an effective amount of a solvent, to form a first solution;

(b) dissolving the agent in an effective amount of a solvent, to form a second solution;

(~~b~~c) ~~dissolving or dispersing~~ adding the ~~agent~~ second solution ~~in~~ to the first solution to form an emulsion and thereby micronize the particles of the agent;

(~~c~~d) freezing the emulsion;

(~~d~~e) drying by vacuum the frozen emulsion to form solid micronized particles of the agent dispersed in solid macromolecular material; and

(~~e~~f) then, dissolving the macromolecular material having dispersed therein solid micronized particles of the agent in an effective amount of a solvent for the macromolecular material to form a dispersion of solid microparticles of agent in the solvent, wherein the solvent is a non-solvent for the agent.

Claim 2 (canceled).

3. (Currently amended) The method of claim 1 further comprising encapsulating the dispersion of solid ~~particles~~ microparticles of agent in an encapsulating material.

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4. (Currently amended) The method of claim 1 wherein greater than 90% of the solid particles are less than 0.2 μm in diameter.

Claim 5 (canceled).

6. (Previously presented) The method of claim 1 wherein greater than 90% of the solid particles are between 10 nm and 1 μm in diameter.

7. (Original) The method of claim 1 wherein the agent is a bioactive agent.

8. (Original) The method of claim 7 wherein the bioactive agent is a protein.

9. (Original) The method of claim 8 wherein the protein is a growth hormone.

10. (Original) The method of claim 8 wherein the protein is an osteoprotegrenin.

11. (Original) The method of claim 7 wherein the agent is selected from the group consisting of peptides, antibiotics, nucleotide molecules, and synthetic drugs.

12. (Original) The method of claim 1 wherein the macromolecular material is a polymer.

13. (Original) The method of claim 12 wherein the polymer is selected from the group consisting of polymers of lactic acid and glycolic acid, polyanhydrides, poly(ortho)esters, polyurethanes, poly(butic acid), poly(valeric acid), poly(caprolactone), poly(hydroxybutyrate), poly(lactide-co-glycolide), poly(lactide-co-caprolactone), and blends and copolymers thereof.

Claim 14 (canceled).

15. (Original) The method of claim 1 wherein step (d) utilizes lyophilization.

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16. (Previously presented) The method of claim 3 wherein the encapsulation is conducted using a process selected from the group consisting of interfacial polycondensation, spray drying, hot melt microencapsulation, and phase separation techniques.

17. (Previously presented) The method of claim 16 wherein the phase separation technique is selected from the group consisting of solvent extraction, solvent evaporation, and phase inversion.

18. (Previously presented) The method of claim 17 wherein the phase inversion technique comprises:

introducing the dispersion into a nonsolvent, wherein the volume ratio of solvent:nonsolvent is at least 1:40, to cause the spontaneous formation of a microencapsulated product, wherein the solvent and the nonsolvent are miscible.

19. (Previously presented) The method of claim 18 wherein the solvent and non-solvent are slightly miscible.

20. (Original) The method of claim 18 wherein the volume ratio of solvent:nonsolvent is between 1:50 and 1:200.

21. (Previously presented) The method of claim 18 wherein the macromolecular material is dissolved in the solvent at a concentration of less than 10% weight per volume and wherein viscosity of the macromolecular material in the solvent is less than 3.5 cP.

22. (Original) The method of claim 20 wherein the concentration of the macromolecular material in the solvent is between 0.5 and 5% weight per volume.

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23. (Previously presented) The method of claim 8 wherein freezing of the emulsion is performed following addition of the agent to the solution at a rate effective to avoid denaturing of the protein.

24. (Canceled)

25. (Original) The method of claim 3 wherein the encapsulating material is a biocompatible polymer.

26. (Original) The method of claim 25 wherein the biocompatible polymer is selected from polyesters, polyanhydrides, polystyrenes, poly(ortho)esters, copolymers thereof, and blends thereof.

Claims 27-33 (Canceled).

34. (Previously presented) The method of claim 1 wherein greater than 90% solid particles are less than 1 μm in diameter.

35. (Previously presented) The method of claim 1, further comprising separating the solid micronized particles of agent from the macromolecular material.

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